Clinical Research and Drug Registration in China and India

September 18-19, 2006 | The Westin Princeton at Forrestal Village, Princeton, NJ

PROGRAM CHAIR
ROMI SINGH, PhD
Global Strategic Regulatory Development
Merck & Co., Inc.

PROGRAM COMMITTEE
PIPASHA BISWAS, MD, MPM DM
Director, Safety Surveillance & Epidemiology
Amgen Inc.

GREGORY E. KALBAUGH, Esq.
Associate Director and Counsel, Intellectual Property, Trade and Labor, U.S.-India Business Council, U.S. Chamber of Commerce

LING SU, PhD
Medical and Pharma Development Director,
Shanghai Roche Pharmaceuticals Ltd., China

SATISH C. TRIPATHI, PhD
Director, Worldwide Regulatory Strategy,
Pfizer Global Pharmaceuticals

Networking Reception
September 18, 5:00-6:30 pm
Industry and regulatory agency participants from China, India, and the US – experts in their fields – will join you and your colleagues in informal and informative conversation.

EXPERT PANEL DISCUSSION
This panel of senior experts from government, industry, academia and leading research organizations will offer stimulating insights on the emerging markets for drug development in India and China – an excellent opportunity to ask questions and interact with representatives on this forum.

CONTACT INFORMATION
Tabletop Exhibits:
Jeff Korn, Phone +1.215.442.6184
e-mail Jeff.Korn@diahome.org

Meeting:
Joanne Wallace, Phone +1.215.442.6180
e-mail Joanne.Wallace@diahome.org

Keynote Address by
WILLIAM HASELTINE, PhD
Founder of Human Genome Sciences and Chairman and Chief Executive Officer Haseltine Global Health.

Special Address by
DAVID A. LEPAY, MD, PhD
Senior Advisor for Clinical Science and Director, Good Clinical Practice Programs Office of Science and Health Coordination Office of the Commissioner, FDA

KEY TOPICS
- Why India and China – Emerging Markets in Drug Development
  Risk/benefit balance
  Challenges and opportunities
- Conducting Clinical Research in India and China: New and Experienced Perspectives
  India and China case studies — when, how, and why
- Logistics and operations of clinical research in China and India
  Are you set up for monitoring? Do you use local, regional or HQ clinical monitors?
  Data management
  Clinical supplies, storage, operations, import of clinical supplies
  IRB approval process
- Strategic Outsourcing and Partnership with China and India – CRO Infrastructure, Analysis and Performance
  Choice — local or global CRO?
  Scope — turnkey or specialized?
- Drug Registration in China and India
  Process of drug registrations
  CSA requirements
  GCP expectations
- Government policy and regulatory environment
  Acceptability of foreign data by FDA
  Trade Related Aspects of Intellectual Property Rights (TRIPS)
  Pharmacovigilance

CONFERENCE OVERVIEW
The conference aims to provide a detailed analysis of what it takes to conduct clinical trials in China and India, and will address: risk/benefit balance; anecdotal experiences of the multinational pharmaceutical industry in China and India; selection and role of CROs; logistics of operations; clinical trials management; government policies (including IPR issues); and pharmacovigilance.

Speakers from various regulatory bodies (including FDA, SFDA, CDSCO), industry experts who have hands-on experience conducting studies in India and China, legal experts, high level government officials from India and China and other highly qualified speakers will present at this conference.

TARGET AUDIENCE
This program has been designed for mid-senior-level management affiliated with the pharmaceutical and biotechnological industry involved in:

- Clinical research and development
- Clinical safety and pharmacovigilance
- Clinical supplies
- Biostatistics
- Data management
- Investigator site management
- Outsourcing management/contract research organizations (CROs)
- Project management
- Medical affairs
- R&D and strategic issues
- Regulatory affairs
- Public policy and law including intellectual property

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!
DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org
SUNDAY • SEPTEMBER 17

6:00-8:00 PM REGISTRATION

MONDAY • SEPTEMBER 18

7:00-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM WELCOME AND OPENING REMARKS
Romi Singh, PhD
Global Strategic Regulatory Development
Merck & Co., Inc.

8:30-10:00 AM SESSION I
WHY INDIA AND CHINA – EMERGING MARKETS IN DRUG DEVELOPMENT
CHAIRPERSON
Romi Singh PhD
Global Strategic Regulatory Development, Merck & Co., Inc.

This session will further examine the highest stakes for clinical research in China and India in terms of profitability, patient population, shaping economic and regulations through production of safe and efficacious drug development.

A NEW PARADIGM FOR DEVELOPMENT OF MEDICAL PRODUCTS
William Haseltine, PhD
Founder of Human Genome Sciences
Chairman and Chief Executive Officer
Haseltine Global Health

Kenneth I. Kaitin, PhD
Director, Tufts Center for the Study of Drug Development
Associate Professor of Medicine
Tufts University School of Medicine, Tufts University

10:00-10:30 AM REFRESHMENT BREAK

10:30-12:30 PM SESSION 2
CONDUCTING CLINICAL RESEARCH IN INDIA AND CHINA:
NEW AND EXPERIENCED PERSPECTIVES
CHAIRPERSON
Naveen Rao, MD
Medical Director, Merck Sharp Dohme Pharmaceuticals

This session focuses on both new and experienced perspectives for conducting clinical research in India and China from industry, case history observations and summaries of clinical practices.

CASE STUDY: MERCK NEW EXPERIENCE IN INDIA
Naveen Rao, MD
Medical Director, Merck Sharp Dohme Pharmaceuticals, India

CASE STUDY: ASTRAZENECA NEW EXPERIENCE IN CHINA
James Cai, MD
Vice President of Research & Development, China
AstraZeneca Pharmaceutical Co., Ltd, China
CASE STUDY: ROCHE PAST EXPERIENCE IN CHINA
Edmund Tsuei, PhD
Head, Pharma Development Operations, Asia-Africa
Deputy Head, Pharma Development Operations, Asia-Pacific-Africa, Roche Products Pty Limited, Australia

CASE STUDY: ELI LILLY PAST EXPERIENCE IN INDIA
Vinod Mattoo, MD, DM
Chief Scientific Officer
Eli Lilly & Company, India

12:30-1:30 PM  LUNCHEON

1:30-3:00 PM  SESSION 3
LOGISTICS AND OPERATIONS OF CLINICAL RESEARCH
CHAIRPERSON
Ling Su, PhD
Medical and Pharma Development Director
Shanghai Roche Pharmaceuticals Ltd.

This session will provide global logistics and operations to address the entire drug development process including clinical trial feasibility, IRBs, clinical supplies, data management, import, export and close-out reports.

CHINA PERSPECTIVE
James Cai, MD
Vice President of Research & Development, China
AstraZeneca Pharmaceutical Co., Ltd, China

INDIA PERSPECTIVE
Vipul Mody, MD, FACP
Clinical Research Director, CNS
Sanofi-Aventis

HEADQUARTERS PERSPECTIVE—CHALLENGES AND OPPORTUNITIES
Michelle M. Shwery, MSc
Director of Clinical Operations, InterContinental Region
Eli Lilly & Company

3:00-3:30 PM  REFRESHMENT BREAK

3:30-5:00 PM  SESSION 4
STRATEGIC OUTSOURCING AND PARTNERSHIP WITH CHINA AND INDIA – CRO INFRASTRUCTURE, ANALYSIS AND PERFORMANCE
CHAIRPERSON
Romi Singh PhD
Global Strategic Regulatory Development, Merck & Co., Inc.

This session will cover all aspects for CRO selection, qualification and partnership to conduct clinical trials in China and India. Case studies will be presented to help facilitate decision making on the selection of local or global CRO for clinical trial services.

GLOBAL CRO
Rajiv Ramanathan
Vice President, Global Sales, Emerging Markets and Site Management Services
Global Clinical Research Organization
Quintiles India

CHINA LOCAL CRO
Mark Engel
Chairman
Excel PharmaStudies, China

INDIA LOCAL CRO
Brijesh Regal
Chief Executive Officer
Apothecaries Limited India

5:00-6:30 PM  NETWORKING RECEPTION

Industry and regulatory agency participants from China, India, and the US – experts in their fields—will join you and your colleagues in informal, and informative, conversation.

TUESDAY • SEPTEMBER 19

7:00-8:00 AM  REGISTRATION

8:00-10:00 AM  SESSION 5
DRUG REGISTRATION IN CHINA AND INDIA
CHAIRPERSON
Satish C. Tripathi, PhD
Director, Worldwide Regulatory Strategy
Pfizer Global Pharmaceuticals

DRUG REGISTRATION PROCESS IN CHINA
Rose Qiu, MD
Medical Director, Global Clinical Operations
Xian-Janssen Pharmaceuticals, Ltd.
Johnson and Johnson, China

DRUG REGISTRATION PROCESS IN INDIA
Romi Singh PhD
Global Strategic Regulatory Development
Merck & Co., Inc.

CSA REQUIREMENTS IN INDIA AND CHINA
Michael Krieg, PhD
Vice President International Regulatory Affairs
Wyeth Pharmaceuticals

10:00-10:30 AM  REFRESHMENT BREAK
10:30-12:30 PM  SESSION 6
TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AND GOVERNMENT POLICIES
CHAIRPERSON
Gregory E. Kalbaugh, Esq.
Associate Director and Counsel
Intellectual Property, Trade and Labor
U.S.-India Business Council
U.S. Chamber of Commerce

This session will address trade-related aspects of intellectual property rights, government regulation and policy, and legal infrastructure in both China and India.

TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) PROTECTION IN BOTH CHINA AND INDIA
Chris Israel, MBA
U.S. Coordinator for International Intellectual Property Enforcement, US Government

CLINICAL AND REGULATORY OF RELEVANCE TO INDIA AND CHINA
Jorge Puente, MD
Vice President, Medical and Regulatory Affairs, Japan and Asia
Pfizer World Headquarters

12:30-1:30 PM  LUNCHEON

1:30-3:30 PM  SESSION 7
REGULATORY AND PHARMACOVIGILANCE
CHAIRPERSON
Pipasha Biswas, MD, MPM, DM
Director, Safety Surveillance & Epidemiology
Amgen, Inc.

This session will deliver information on government policy, regulation and pharmacovigilance. Government officials and leading industry speakers will engage and reach for high-level discussion on acceptability of foreign data, GCP inspections and pharmacovigilance.

SPECIAL ADDRESS:

ACCEPTABILITY OF FOREIGN DATA AND GOOD CLINICAL PRACTICE (GCP) INSPECTIONS
David A. Lepay, MD, PhD
Senior Advisor for Clinical Science and Director, Good Clinical Practice Programs, Office of Science and Health Coordination, Office of the Commissioner, FDA

PHARMACOVIGILANCE IN CHINA AND INDIA

Pipasha Biswas, MD, MPM, DM
Director, Safety Surveillance & Epidemiology
Amgen, Inc.

3:30-3:45 PM  REFRESHMENT BREAK

3:45-5:00 PM  SESSION 8
MODERATOR
Peter K. Honig, MD, MPH
Executive Vice President, Worldwide Regulatory Affairs and Product Safety, Merck and Company, Inc.

PANEL DISCUSSION: OPPORTUNITIES AND CHALLENGES FOR CONDUCTING CLINICAL TRIALS IN CHINA AND INDIA

A panel of senior level experts from government, industry, academia and leading research organizations will offer exciting and interactive discussion on the emerging markets for drug development in India and China - an excellent opportunity to ask questions and interact with representatives on this forum.

5:00 PM  CONFERENCE ADJOURNED
GROUP DISCOUNTS*
Register 3 individuals from the same company and receive complimentary registration for a 4th!

All 4 individuals must register and prepay at the same time – no exceptions.
DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.

To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

TRAVEL AND HOTEL
The most convenient airport is either Newark or Mercer Airport and attendees should make airline reservations as early as possible to ensure availability. The Westin Princeton at Forrestal Village is holding a block of rooms at the reduced rate below until August 28, 2006, for the DIA meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $169  Double $169

Please contact the Westin Princeton at Forrestal Village by telephone at +1.609.452.7900 or by fax at +1.609.452.1223 and mention the DIA meeting.
The hotel is located at 201 Village Boulevard, Princeton, NJ 08540, USA.

UNITED AIRLINES & US AIRWAYS
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To obtain schedule information and the best fares, call United Airlines’ Specialized Meeting Reservations Center at 1-800-521-4041. Make sure you refer to Meeting ID Number 571AK. Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

Participants with Disabilities: DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.

DRUG INFORMATION ASSOCIATION  http://www.diahome.org

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Clinical Research and Drug Registration in China and India

Meeting ID #06034
The Westin Princeton at Forrestal Village
Princeton, NJ, USA
SEPTEMBER 18-19, 2006

Register online or fax this page to +1-215-442-6199

CONTACT & TABLETOP EXHIBIT INFORMATION
Attendees may visit the tabletop exhibits during the meeting and during receptions (if applicable).
Meeting information: Contact Joanne Wallace at the DIA office by telephone +1-215-442-6189, fax +1-215-442-6199 or email Joanne.Wallace@diahome.org.
Tabletop exhibit information: Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahome.org. For tabletop exhibit space, please check the box below.

GROUP DISCOUNTS (not available online or on already discounted fees)
Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions. See page 5 for complete details.

Registration Fees
If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

MEMBER EARLY-BIRD OPPORTUNITY
Available on nondiscount member fee only
On or before AUG. 28, 2006 After AUG. 28, 2006
Member Fee US $1125 ☐ US $1300 ☐

Join DIA now to qualify for the early-bird membership fee! www.diahome.org/docs/Membership

MEMBERSHIP US $130 ☐

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee US $1430 ☐

A one-year membership to DIA is available to those paying a NONMEMBER meeting registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ☐ I do NOT want to be a DIA member ☐

Discount Fees
Government (Full-time) US $300 ☐ US $430 ☐
Charitable Nonprofit/Academia (Full-time) US $650 ☐ US $780 ☐

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

CANCELLATION POLICY: On or before SEPTEMBER 12, 2006
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200 Government or Academia or Nonprofit (Member or Nonmember) = $100
Cancellations must be in writing and be received by the cancellation date above.
Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

I cannot attend but please keep me informed of DIA’s future events. (requires completion of name, postal address and email address on this form)

REGISTRATION FORM

Please check the applicable category:
☐ Academia ☐ Government ☐ Industry ☐ CSO ☐ Student (Call for registration information)

Last Name ☐ Check if part of group registration ☐ First Name ☐ Middle Initial
M.I.

Degrees ☐ Dr. ☐ Mr. ☐ Ms.

Job Title

Company

Address ☐ As required for postal delivery to your location ☐ Mail Stop

City ☐ State ☐ Zip/Postal ☐ Country

email ☐ Required for confirmation

Phone ☐ Fax ☐ Number ☐ Required for confirmation

Group Registrant #2 Last Name ☐ First Name ☐ Completed form required for each group registrant

Group Registrant #3 Last Name ☐ First Name ☐ Completed form required for each group registrant

Group Registrant #4 Last Name ☐ First Name ☐ Completed form required for each group registrant

PAYMENT OPTIONS
Register online at www.diahome.org or check payment method

☐ CREDIT CARD number may be faxed to +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX
Exp Date __________________________

Card # __________________________

Signature __________________________

☐ CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 950000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

☐ BANK TRANSFER When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Meeting ID # must be included on the transfer document to ensure payment to your account.

Keynote Address by
WILLIAM HASELTINE, PhD
Founder of Human Genome Sciences

Networking Reception
September 18, 5:00-6:30 PM

Expert Panel Discussion

DRUG INFORMATION ASSOCIATION
800 Enterprise Road, Suite 200
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